Message

From: Tanner, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85D9A3F12DFA4B4ABAAE51BC4723EDDB-TANNER, BARBARA]
Sent: 3/28/2019 4:39:12 PM
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Subject: News Articles (For EPA Distribution Only)

BNA.COM ARTICLES

Supreme Court Considers Reducing Regulatory Agency Power (1)

By Greg Stohr and Jennifer A. Dlouhy
Posted March 27, 2019, 11:31 AM Updated March 27, 2019, 2:28 PM

The U.S. Supreme Court's conservative justices expressed doubts about a precedent that business groups and the Trump administration say gives federal agencies too much power to change regulations without notice.

Wheeler To Face Appropriators in First Hill Test as EPA Head

By Abby Smith
Posted March 27, 2019, 12:42 PM

EPA Administrator Andrew Wheeler will face House appropriators April 2 to defend the Trump administration's fiscal 2020 budget request, which again seeks deep cuts to the agency's budget and staffing levels.

EPA Defends Shifting Staff Between Chemical Risk Efforts

By Sylvia Carignan
Posted March 27, 2019, 1:15 PM

The EPA attempted to justify its decision to shift chemical risk assessment staff toward a program that determines whether chemicals should be restricted, responding to concerns raised March 27 by a House subcommittee leadership.

Embalmers Face Challenge With EU Formaldehyde Limit

By Stephen Gardner
Posted March 27, 2019, 1:34 PM

Embalmers could face the toughest challenge from new European Union limits on workplace exposure to cancer-causing substances approved by the European Parliament March 27.

EPA Rule Barring Grant Recipients From Boards Beats Another Suit

By Mike Leonard
Posted March 27, 2019, 1:59 PM

A rule change banning recipients of Environmental Protection Agency grants from serving on the agency's scientific advisory boards survived a court challenge by the Union of Concerned Scientists.

Plastic Plates, Cutlery to Be Banned in Europe as of 2021

By Stephen Gardner (Bloomberg Environment) and Jonathan Stearns (Bloomberg)
Posted March 27, 2019, 2:36 PM

The European Union decided to ban plastic consumer items including plates, cutlery, and straws as of 2021 to help clean up oceans.

Ban on Single-Use Plastic Bags Seen Likely in New York State

By Keshia Clukey
Posted March 27, 2019, 4:26 PM

New York State is poised to ban single-use plastic bags, legislators and environmental advocates announced March 27.

Bayer Loses Second Trial Over Claims Roundup Causes Cancer

By Joel Rosenblatt and Robert Burnson
Posted March 27, 2019, 6:12 PM

Bayer AG lost a second trial over claims its Roundup weed killer causes cancer, increasing pressure on the company to spend billions of dollars to settle thousands of similar lawsuits.

High Court Could Take First Step to Chevron Doctrine's Demise

By Kimberly Strawbridge Robinson
Posted March 28, 2019, 4:56 AM

The U.S. Supreme Court justices appear primed to curtail administrative agencies' regulatory power, but the court's ultimate decision could lead to a much bigger conservative target: overturning the oft-maligned Chevron doctrine.

INSIDEEPA.COM ARTICLES

Justices Grapple With Whether To Narrow EPA Regulatory Deference

March 27, 2019

Supreme Court justices at March 27 oral argument appeared unlikely to completely overturn a key precedent granting deference to EPA and other federal agencies' interpretations of their regulations, though several of the justices appeared open to the Trump administration's call to narrow the deference.

At issue in *Kisor v. Wilkie*, a case involving the Department of Veterans Affairs, is whether the justices should overturn the precedent set by a 1945 ruling *Bowles v. Seminole Rock & Sand Co.* and its 1997 successor Auer v. Robbins, which says judges should defer to agencies' "reasonable" interpretations of ambiguous provisions in their rules.

The Justice Department (DOJ) agrees with opponents of the deference doctrine that it has been applied too broadly, but the department says those concerns can be addressed through strict new limits on when deference is appropriate, rather than by overturning it altogether. While EPA is not involved in the case, any high court ruling that either narrows or terminates the deference doctrine could put major constraints on the agency's rulemaking powers.

During questioning of Kisor attorney Paul Hughes, Justices Stephen Breyer, Elena Kagan and Sonia Sotomayor were vocal in their opposition to overturning *Auer*. And Justice Ruth Bader Ginsburg questioned the effects on the lower courts of overturning *Auer*.

Chief Justice John Roberts and Justice Samuel Alito raised questions about overturning Supreme Court precedent, with Roberts appearing to be open to some change and Alito asking both Hughes and Solicitor General Noel Francisco what they thought the effect of overturning *Auer* would be.

During questioning of Francisco, Justices Neil Gorsuch and Brett Kavanaugh suggested *Auer* needs further revision, with Kavanaugh suggesting that judges find it easier to defer to agency interpretation than wrestle with whether that interpretation is reasonable.

Speaking to Hughes, Breyer was critical of the argument that instead of relying on an agency's interpretation, judges should decide whether a rule is correct. "I mean, I want to parody it, but, I mean, this sounds like the greatest judicial power grab since *Marbury v. Madison*, which I would say was correctly decided," Breyer said.

Kagan questioned whether there was a good enough reason to overturn *Auer* and *Seminole Rock*, noting that in the many years since *Seminole Rock*, Congress could have changed the deference principle but has not. "That's a reason for us to say, you know, we don't think that we should step in where Congress has not," she said.

Hughes responded that Auer did not have any underpinning when it was announced, and that it has never been reconciled with the Administrative Procedure Act (APA).

"Its underpinning is agency expertise. Its underpinning is an idea that judges are far less suited to make these kind of minute decisions of agency policy than agency decision-makers are," Kagan countered.

Breyer then jumped in to say that *Auer* repeats *Seminole Rock*, which was decided before the APA was enacted. "Wouldn't somebody have said something about it if, in fact, those words were meant to change what was pretty well established law at the time?"

Longtime Precedent

Sotomayor said the concept of agency deference goes back even further than *Seminole Rock*, saying she could cite a series of cases through the 1800s "where the courts were basically talking about [taking] the interpretation of the agencies unless some manifest error was present."

"Regulated parties should know where to start, and the best people who can tell them is the agency who's responsible to the public for having sound interpretations or reasonable interpretations," Sotomayor said.

Ginsburg questioned whether, if *Auer* is overturned, lower courts would see a huge uptick in cases because they had previously relied on *Auer*, and the losing party might return to court to argue the decision was incorrect because "Auer is not good law."

Hughes said parties could potentially advance such arguments, "but I don't think that increases instability any more than exists in the status quo, when those decisions are already subject to revision by the agency."
Alito asked Hughes, if *Auer* is overturned, whether an agency's interpretation, particularly in areas requiring a great deal of scientific or technical knowledge, should be entitled to no deference by a court.

Hughes replied that agencies would still be allowed some deference under *Skidmore v. Swift & Co.*, a 1944 Supreme Court ruling that said an administrative agency's interpretative rules deserve deference according to their persuasiveness.

But Kavanaugh said "*Skidmore* deference, as I've seen it applied over many years, is not much" deference.

Roberts, touching on the *stare decisis* question, which cautions against overturning judicial precedent, said, "I think the issue depends at least in part about how much of a change you're making," he said, adding that he has difficulty understanding what *Skidmore* deference is.

Questioning Francisco, Gorsuch said, "As I understand it, nobody left before us alive is willing to take *Auer* literally, and it's just a matter of how much revision to it we've already made. Is it enough? How much further should we go? Or should we just give up on it altogether?"

DOJ Proposal

Gorsuch also asked whether DOJ's proposed multi-factor test for a narrower interpretation of *Auer* is "a recipe for stability and predictability in the law, or is that a recipe for the opposite?"

DOJ in a brief to the court argued in part that "a reviewing court should defer to the agency's interpretation only if the interpretation was issued with fair notice to regulated parties; is not inconsistent with the agency's prior views; rests on the agency's expertise; and represents the agency's considered view, as distinct from the views of mere field officials or other low-level employees."

Francisco replied that it is absolutely a workable standard. "The requirement of genuine ambiguity is really what we think this Court's cases have always required, although there is language that we think ought to be replaced with the genuine ambiguity language."

But Gorsuch said parties fight over whether there is ambiguity and what ambiguity means, they fight over what reasonableness means and how consistent is consistent, and that if the court were to accept DOJ's proposal, in which every agency could define relevant evidence differently, "I'm just wondering, at what point does this whole edifice just fall upon itself?"

Gorsuch added that while DOJ says its approach would benefit regulated parties and their private reliance interests, "I must say I cast a skeptical eye when the government is worried about private reliance interests" because "every private party before us says their interests in stability would be better served by eliminating this rule altogether."

Kavanaugh asked Francisco why federal agencies can't just do notice and comment on all rules, especially if there was a way to make notice and comment more efficient. "Do you agree from your study of this issue that the impediments to efficient notice-and-comment rulemaking have pushed the government into doing more things in this manner?"

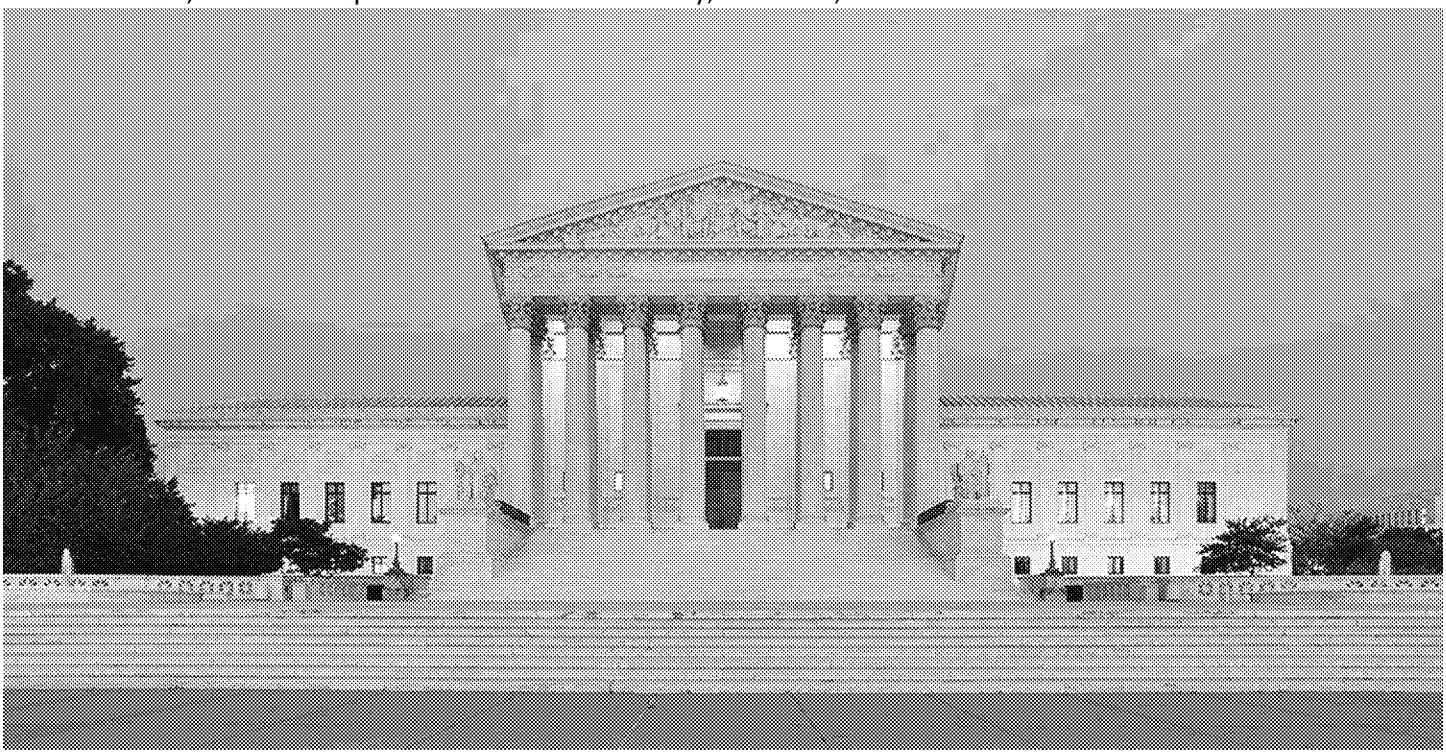
"Your Honor, I'm not prepared to say I agree or disagree with that. I certainly understand Your Honor's point," Francisco replied. -- *Lara Beaven* (lbeaven@iwpnews.com)

https://insideepa.com/daily-news/justices-grapple-whether-narrow-epa-regulatory-deference

GREENWIRE ARTICLES

Deference rule: Good sense or bureaucratic 'sideswipe'?

Ellen M. Gilmer, E&E News reporter Published: Wednesday, March 27, 2019



The Supreme Court in Washington, D.C. Joe Ravi/Wikimedia Commons

Supreme Court justices appeared reluctant today to strike down a long-standing legal precedent that favors agency interpretations of their own rules.

During oral arguments in *Kisor v. Wilkie*, the court grappled with what's known as the *Auer*standard, which directs judges to defer to agencies when they're interpreting their own murky rules. Critics are asking the justices to eliminate the doctrine.

The case, which stems from a veterans' benefits dispute, could have broad implications for environmental policy, energy regulations and administrative law in general, as the deference rule arises often in those areas ***Greenwire***, March 25).

Many court watchers view the case as a test of the justices' treatment of administrative agencies after the court shifted to the right on the ideological spectrum last year.

Conservatives have been gunning for *Auer* and similar deference rules for years, saying they violate both the constitutional separation of powers and the Administrative Procedure Act. They hoped Justice Brett Kavanaugh's confirmation would help spur the standards' demise.

But the court appears divided on multiple issues.

Several justices from the court's liberal wing defended *Auer*, at least in part, and signaled that they likely would not support a full reversal.

"*Auer* does not call for blind deference," Justice Ruth Bader Ginsburg told Mayer Brown LLP attorney Paul Hughes, who represents the veteran fighting the precedent.

Justice Stephen Breyer rattled off technical details about rules from the Food and Drug Administration and Federal Communications Commission.

"Do you know how much I know about that?" he said, adding later: "Exactly."

'Sideswipe of a bureaucracy'

That's the argument for keeping *Auer* in place: Expert agencies know more about their issues than federal judges do.

But Justice Neil Gorsuch, an ardent critic of deference rules, rejected the logic, maintaining that many agency interpretations accepted by courts are a "sideswipe of a bureaucracy."

Vulnerable members of the public, including immigrants and veterans, deserve a setup in which independent judges have the final say on the appropriate interpretation of an agency rule, Gorsuch said.

The Trump administration has called for a middle ground, maintaining the standard but clarifying limits on its application.

The government's approach would have judges weigh additional factors before deferring to an agency interpretation, including whether the agency's approach was carefully considered and whether the public had fair notice.

Gorsuch appeared skeptical of the approach, questioning the government's contention that it would lead to more consistency in regulatory interpretation.

"Or is that a recipe for the opposite?" he asked.

Hughes, the lawyer opposing *Auer*, called the government's proposal "better than the status quo" but insufficient to address Administrative Procedure Act problems.

A Supreme Court case called *Seminole Rock* that formed the foundation of the deference standard predated the APA, and the court never reconciled the two, Hughes said.

Under the APA, the public is entitled to involvement in many agency decisions. But knowing they'll receive deference, Hughes said, many agencies sidestep that process and reach interpretations outside the public eye.

'It's been on the books for decades'

The justices also struggled with the implications of scrapping decades of precedent. *Auer* was decided in 1997, but its precursor case was decided in 1945, and Justice Sonia Sotomayor noted that other cases applied similar deference tests in the 1800s.

Justice Elena Kagan said the court usually overturns cases only when a precedent is causing dramatic problems.

"Do you think *Auer* rises to that level?" she asked skeptically. She added that Congress had years to take action on the issue and has "shown no interest whatsoever in reversing the rule the court established."

And what about the many lower court decisions that would be "thrown into doubt"? Justice Samuel Alito asked.

Solicitor General Noel Francisco stressed the importance of stare decisis, the court's practice of respecting precedent.

"It's been on the books for decades," Francisco said.

Hughes responded that the impacts on lower court decisions would create no more legal instability than what already exists in a system that allows agencies to change their interpretations so easily.

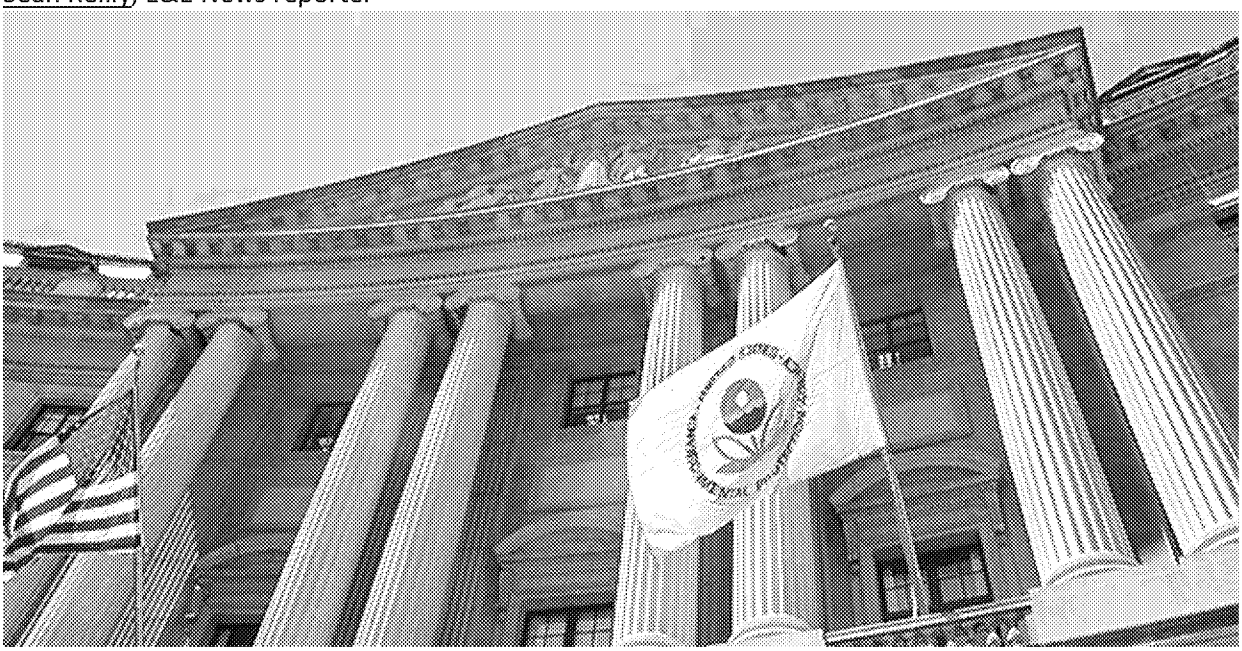
Kavanaugh and Chief Justice John Roberts also appeared troubled with how judges would replace *Auer*. A weaker standard called *Skidmore* could come into play; there, judges defer to agency interpretations that are persuasive.

"That's not really deference," Kavanaugh said.

https://www.eenews.net/greenwire/2019/03/27/stories/1060131081

For 3rd time, judge tosses suit over advisory panel makeup

Sean Reilly, E&E News reporter



EPA headquarters in Washington. NRDC/Flickr

Published: Wednesday, March 27, 2019

A federal judge today dismissed a third lawsuit challenging a far-reaching EPA restriction on advisory committee membership, likely dealing a fatal blow to opponents' hopes of overturning the policy anytime soon.

In the **ruling**, U.S. District Judge F. Dennis Saylor said the Union of Concerned Scientists had failed to show that the 2017 directive by then-EPA Administrator Scott Pruitt violated the Administrative Procedure Act. Saylor, based in the District of Massachusetts, also said the Boston-based advocacy group had failed to state a legal claim for which relief could be granted.

The group, often known by its acronym UCS, filed the suit in January 2018, three months after Pruitt had generally barred EPA grant recipients from serving on agency advisory committees. Federal judges in other states also recently threw out two challenges brought by a variety of other organizations. Taken together, the three rulings make it probable that the policy will survive through the end of President Trump's current term in January 2021.

In an email, EPA spokesman James Hewitt said the agency is reviewing the decision and is pleased that Saylor granted its dismissal motion.

UCS's Genna Reed said the group is looking at its appeal options and again blasted the policy as unjustified on scientific or ethical grounds.

"It's clearly meant to achieve political ends, not help agencies get the best advice," Reed, lead science and policy analyst for UCS's Center for Science and Democracy, said in a statement.

In ordering the ban, Pruitt said it was intended to ensure the objectivity of members of almost two dozen federal advisory committees that provide outside expertise to EPA on a range of issues. Pruitt and Andrew Wheeler, his successor as EPA administrator, have cited the policy in reshaping the membership of two particularly important panels, the Clean Air Scientific Advisory Committee and the Science Advisory Board.

Joining the Union of Concerned Scientists as a plaintiff in its suit was a now-former member of the air committee.

But documents released in another of the three lawsuits indicated that Pruitt had relied heavily on input from Republican lawmakers and trade groups in devising the policy (***Greenwire***, May 24, 2018).
An E&E News review last fall found that the agency has made little or no attempt at enforcement at many other lower-profile advisory committees (***Greenwire***, Sept. 21, 2018).

https://www.eenews.net/greenwire/2019/03/27/stories/1060131073

'I am mentally calculating my retirement date here' — judge

Ellen M. Gilmer, E&E News reporter

Justice Department lawyer Jonathan Brightbill (bottom) argues before the 9th U.S. Circuit Court of Appeals yesterday in San Francisco. 9th Circuit

Published: Wednesday, March 27, 2019

Eleven federal judges were at times puzzled, perturbed and bemused during high-stakes oral arguments yesterday involving the pesticide chlorpyrifos.

"Counsel, I am mentally calculating my retirement date here," Judge Morgan Christen deadpanned to Trump administration lawyer Jonathan Brightbill halfway through the hourlong session.

Christen was airing frustration about EPA's decision to freeze certain agency proceedings on chlorpyrifos last summer — on top of environmentalists' claims that it has already dragged its feet for years.

"Is there no limit to this?" the Obama appointee asked at another point. "Is that really your answer?"

The often-combative court session yesterday afternoon at the 9th U.S. Circuit Court of Appeals centered on EPA's 2017 denial of environmental and civil rights groups' petitions to ban chlorpyrifos, which is used on U.S. crops and has been linked to neurological problems in children.

Following a lawsuit from the League of United Latin American Citizens, environmentalists and farmworkers' groups, a three-judge panel last year ordered EPA to ban the use of the farm chemical on food crops.

But the 9th Circuit in February agreed to reconsider the case before a bigger group of judges — a practice reserved for especially consequential cases.

The 11 judges grilled both sides, questioning Earthjustice lawyer Patti Goldman on whether the court even had jurisdiction over the dispute and cornering Brightbill on how long it would take EPA to issue a final decision.

Jurisdiction

Advocates first pushed for a ban on chlorpyrifos on food crops in 2007. They argue EPA is required under the Federal Food, Drug and Cosmetic Act to first determine that a chemical is safe before allowing its use on food.

The Obama administration proposed a rule blocking the pesticide but failed to finalize it before President Trump took office.

In 2017, then-Administrator Scott Pruitt denied the petition. But the agency never acted on subsequent objections filed by supporters of a ban.

Several judges grappled yesterday with whether EPA must finish processing those objections before the court has jurisdiction.

"Is it still your position that we get to merits even though there's been no ruling on the objections?" asked Judge Richard Paez, a Clinton appointee.

"The only step that isn't completed is a decision by EPA on those objections. ... That's outside our control," New York Deputy Solicitor General Andrea Oser — representing states that support a ban — told the court.

George W. Bush-appointed Judge Carlos Bea and others asked whether, given the question about EPA's incomplete proceedings, the advocates should have sought the ban through what's known as a writ of mandamus from the court, rather than a routine legal complaint.

Goldman responded that her clients were concerned that such an approach would end up actually bogging down the process, as the lawsuit was already set for streamlined review.

The court has the authority to effectively accept the groups' complaint as a writ request, she said.

'Whoa, whoa, counsel, wait a second'

Brightbill, the DOJ lawyer, pushed for the court to toss the case on jurisdictional grounds.

He triggered the frustration of several judges, however, when he noted that EPA paused its consideration of the petitioners' formal objections when the three-judge panel issued its ban order last summer.

"You're saying that after the panel issued its rulings, the government decided not to proceed on parallel tracks?" asked Judge Jacqueline Nguyen, an Obama appointee.

Brightbill contended that the panel's ruling rendered the objections moot. But the fact that EPA hasn't issued a decision on those objections is also why the court lacks jurisdiction over the case, he said, maintaining that there hasn't been a final agency action — a threshold for getting into court.

The government lawyer stressed that EPA would be ready to take final action within 90 days of the 9th Circuit's ruling in this case.

"There aren't going to be any surprises in the next 90 days that would change anything, other than the EPA would make a final decision, correct?" Clinton-appointed Judge M. Margaret McKeown asked.

Brightbill said "it is fully their intent" to act within 90 days.

"Whoa, whoa, counsel, wait a second. I was a prosecutor for a long time, and whenever you hear, like, 'It is the intent to do something,' that's not the same as 'We're going to do it,'" said Judge John Owens, an Obama appointee.

"Is the answer yes or no?" he added. "Not 'We hope to, we intend to, we mean to.' Yes or no, will it be done in 90 days?"

"Yes," barring extraordinary circumstances, Brightbill responded.

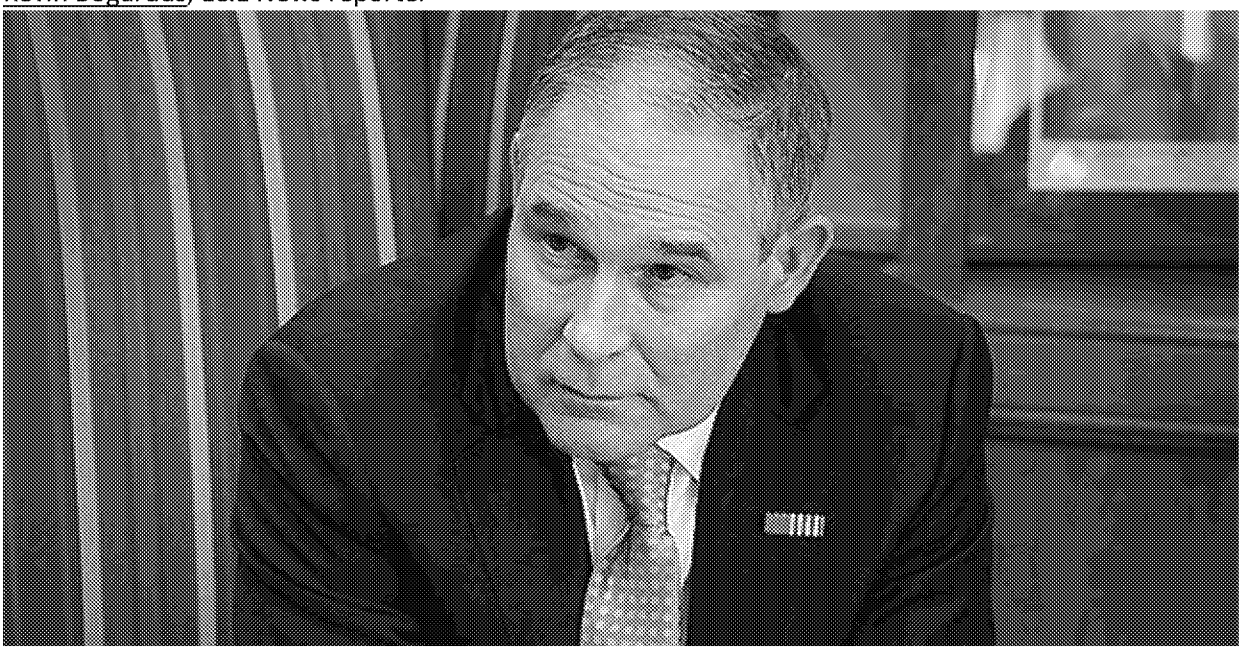
The environmentalists and other advocates are pushing the 9th Circuit to order EPA to either determine that chlorpyrifos is safe or grant their requests to finalize a ban within 60 days.

The court is expected to issue a ruling in the coming months.

https://www.eenews.net/greenwire/2019/03/27/stories/1060130957

Ethics office won't certify Pruitt report on condo rental

Kevin Bogardus, E&E News reporter



Former EPA Administrator Scott Pruitt. EPA

Published: Wednesday, March 27, 2019

The federal government's chief ethics office has declined to certify a financial disclosure report filed by former EPA Administrator Scott Pruitt — an aftereffect of his rental of a Capitol Hill condo tied to a lobbyist with business before the agency.

In a note added last week to Pruitt's **report**, David Apol, general counsel for the Office of Government Ethics, said the agency was unable to determine whether Pruitt received a reportable gift related to his rental of the condo.

The EPA inspector general "inquiry into the matter was closed without resolution. Therefore, OGE declines to certify," Apol said in his note, dated March 20.

EPA's internal watchdog had interviewed witnesses and reviewed records as part of its investigation into Pruitt's condo lease and whether it constituted a gift. The IG coordinated with OGE and consulted with the Justice Department on the matter, as well.

Pruitt resigned from EPA in July last year before he was interviewed by investigators, leading the IG to close the case and deem it inconclusive.

Don Fox, former general counsel and acting director of OGE, said the ethics office's declining to certify Pruitt's report shows there was doubt at the agency as to whether his relatively low-market rental of the apartment was "an inappropriate gift or gratuity."

"That means the [OGE] director believes Pruitt has not disclosed everything or is not in compliance with ethics laws, or both. Those are the inferences you can draw from the form," he said.

Pruitt's report covers the 2017 calendar year, when he lived part of that time in the condo. He paid rent only when he stayed there, at a rate of $50 per night. Pruitt's landlord was the wife of lobbyist Steven Hart, who often had contact with EPA during Pruitt's time in the condo, including a meeting with the then-administrator, but Hart has disputed that he was lobbying the agency (***E&E Daily***, April 23, 2018).

Cleta Mitchell, a partner at Foley & Lardner LLP who helped set up Pruitt's legal defense fund, told E&E News in an email last December that she was in "steady communications" over several months with the EPA ethics office regarding Pruitt's financial disclosure report. The report itself shows it was revised several times in September before it was first released to the public.

Mitchell declined to comment when contacted today for this story.

Under OGE regulations, if the ethics agency reviews a filer's financial disclosure report and needs more information, it is supposed to notify the filer's agency and ask for that information. An OGE spokeswoman declined to comment for this story.

EPA press officials didn't respond to questions from E&E News.

On his financial disclosure report, which was filed after his resignation, Pruitt said he knew EPA and OGE had discussed whether "certain actions or activities during 2017" might be gifts to him that should be included on his report.

"To the extent that I am aware of specific allegations, I dispute the facts asserted and, accordingly, am not aware of reportable gifts," Pruitt said.

Kevin Minoli, then EPA's designated agency ethics official, signed off on the report. He, however, cited OGE rules that his review was not an audit and that a filer's disclosures should be taken at "face value" as correct in his own note.

Pruitt also noted on the report that there was an inventory of items he received as head of EPA that remained at the agency. Through litigation, Citizens for Responsibility and Ethics in Washington obtained a nine-page **list** of those gifts to Pruitt.

Democratic senators seized on the decision by OGE not to certify Pruitt's financial disclosure report, saying the EPA IG had let "unethical behavior" at the agency slide without punishment.

"The Office of Government Ethics decision is appropriate and important, but it only underscores why the EPA Office of Inspector General needs to take ethics issues more seriously," said Sens. Tom Carper (D-Del.) and Sheldon Whitehouse (D-R.I.) in a joint statement yesterday.

"OGE has no authority to conduct investigations of misconduct at EPA. When the EPA IG fails to fully investigate ethical violations brought to its attention, it signals there are no consequences for unethical behavior by EPA officials."

The senators said they hoped OGE would also not certify Pruitt's **termination report**, where he reported his legal defense fund had received last year a $50,000 contribution from billionaire businesswoman and Republican donor Diane Hendricks, which wasn't reviewed by EPA ethics officials.

Asked for reaction to Carper and Whitehouse's criticism of the EPA IG, Jeff Lagda, a spokesman for the watchdog office, had no comment.

Lagda did tell E&E News that other IG reviews related to Pruitt will be forthcoming this year. Audits of Pruitt's travel and his use of a special hiring authority to bring on close aides and award raises are both expected to be issued in the spring, while an audit of EPA's preservation of emails and text messages is anticipated this summer, he said.

As to what happens now related to Pruitt's noncertified report, likely there will be nothing more. Fox, formerly with OGE, noted that the EPA IG has closed its investigation into the former EPA chief's rental of the condo.

"It probably just remains as status quo, that OGE was not satisfied with his compliance and that is where the matter ends," Fox said.

https://www.eenews.net/greenwire/2019/03/27/stories/1060131093

Reagan appointee says EPA 'disemboweling' program

Corbin Hiar, E&E News reporter

House Science, Space and Technology Committee lawmakers yesterday scrutinized EPA's chemicals programs. Claudine Hellmuth/E&E News

Published: Thursday, March 28, 2019

A federal investigator who spent a year auditing EPA's chemical testing program yesterday still couldn't explain how or why agency leaders decided against releasing a completed review of the dangers posed by the widely used chemical formaldehyde.

"There are questions about what happened to it," Alfredo Gómez, director of the Government Accountability Office's natural resources and environment team, told lawmakers at a House Science, Space and Technology subcommittee hearing.

Also unclear, the GAO witness said, is "when it is going to be released."

While Republicans and a career EPA official supported leadership's efforts to delay the draft formaldehyde report, a Reagan-era political appointee argued they were destroying the agency's Integrated Risk Information System.

IRIS has been working on the draft formaldehyde risk assessment since 1997. The chemical, which a Department of Health and Human Services program determined in 2011 is "known to be a human carcinogen," is used in everything from plywood to insecticides.

IRIS was ready to unveil its long-awaited formaldehyde review last year. But EPA leaders blocked the science-focused program from releasing any of its research, GAO reported earlier this month (***E&E News PM***, March 4).

Such assessments are often used by regulatory offices at EPA and other federal and state agencies to limit the use of potentially dangerous chemicals.

Gómez began auditing IRIS last March. He found EPA leadership verbally ordered program offices to limit their assessment requests to no more than four chemicals after an initial agencywide survey found broad support for most of IRIS's work.

The end result of that process was a **work plan** for IRIS that didn't include formaldehyde or 10 other chemicals.

Rep. Don Beyer (D-Va.) pressed the top career official overseeing IRIS for more information on how that second review of the program's work plan came about.

Jennifer Orme-Zavaleta, EPA's science adviser, during a hearing yesterday. House Science, Space and Technology Committee

"I wasn't involved in that conversation," said Jennifer Orme-Zavaleta, the principal deputy assistant administrator for science in EPA's Office of Research and Development. "I don't know if it was requested by the ORD representatives or the administrator."

Beyer suggested the move to withhold the formaldehyde assessment was made to appease the former clients and employers of EPA leadership.

"The suspicious part of me wonders if the prioritization wasn't simply used as a way to eliminate chemicals that are controversial within industry and focus on ones that are easy, low-hanging fruit," he said.

EPA's Office of Pollution Prevention and Chemical Safety is currently working on a risk assessment of formaldehyde, the first step toward potential regulations of the chemical — but is doing so without first releasing IRIS's completed draft review (***Greenwire***, March 20).

The situation, Beyer said, "raises the prospect that this is not science driving it, but rather the politics and money."

Although Orme-Zavaleta couldn't offer much clarity on the status of IRIS's formaldehyde assessment, overall she described the politically directed surveys of the program's priorities as a positive step.

"We have always gone out to programs in helping to identify what their needs are," she said. "But this new process raises it to an assistant administrator level. And that's going to provide greater stability to the program as well as greater accountability."

Republican lawmakers on the Science Committee also backed EPA leadership's IRIS efforts. GAO found these moves had shrunk the workload of the program from 22 chemicals to 11 and effectively prevented it from publicly releasing any work for six months.

"A brief pause may have been necessary to adequately address the issues and challenges that IRIS faces and develop a plan of action for future progress," said Rep. Ralph Norman (R-S.C.), who noted the program has been on GAO's High Risk List since 2009 (***Greenwire***, March 6).

"You suspend operation and pull the cars off the track for evaluation, which makes for a better ride in the end," Norman said.

But that analogy didn't match up with what GAO's most recent review found was needed. It mainly called for greater leadership support of IRIS's scientific focus.

"As we understand it, the IRIS program was able to handle that workload given their current resources," Gómez said, referring to the 22 chemicals it was reviewing in early 2018.

Bernard Goldstein, who was the assistant administrator for EPA's ORD under President Reagan, was even more dismissive of the efforts by the Trump EPA to reform IRIS.

"Rather than streamlining, disemboweling is really what's happening here," he said.

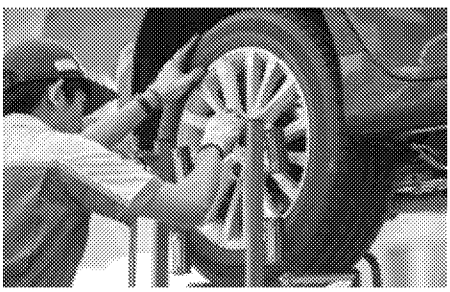
https://www.eenews.net/eedaily/2019/03/28/stories/1060131809

CHEMICAL WATCH ARTICLES

Echa pressed to clarify reevaluation of resorcinol

Group seeks legal clarity on French proposal

27 March 2019 / Europe, REACH



Counsel acting for the Resorcinol Task Force has written to Echa seeking legal clarity on its decision to allow the substance to be evaluated by another member state.

In 2017 Finland concluded its evaluation under the community rolling action plan (Corap), having investigated concerns that it is a potential endocrine disrupting chemical.

In its conclusion, the Finnish Safety and Chemicals Agency (Tukes) confirmed that resorcinol may affect thyroid function, but decided not to ask for more test data. It viewed that available test methods would not yield additional information of value.

Instead it opted for a risk management option analysis (RMOA) to help decide whether it could be considered as a substance of equivalent concern and thereby proposed for restriction under REACH.

However, this month a French proposal to revisit the substance's endocrine disrupting properties in the environment was added to the updated community rolling action plan (Corap).

In a 21 March statement, the Resorcinol Task Force said it was disappointed that "neither the legal basis nor the legal merits of the case for reinclusion of resorcinol have been further explained".

This, it added, is despite a recent letter to Echa from the legal counsel acting for the group, seeking such clarification.

The justification issued by France "does not seem to add to the arguments" already put forward at Echa's Member State Committee (MSC) meeting in February, the statement said. And it "remains far short of providing the evidence necessary to support such an exceptional move".

It is unclear, the group added, as to why the responsibility for overseeing the extended substance evaluation would switch to France rather than stay with Finland. "This brings into question whether the existing substance evaluation has been re-opened or a new one has been initiated. These are important matters to determine from a legal perspective."

The taskforce said it is ready to commission work to fill any identified data gaps. However, it added, such a commitment must be dependent on a reliable test protocol. "There are elements of the current Lagda [Larval Amphibian Growth and Development Assay] studies protocol which could jeopardise the validity of any result and these would need to be taken into account before any decision was reached to avoid unnecessary animal testing."

Although resorcinol is used at low levels in hair dyes and cosmetic products, its primary use is in tyres and as an industrial intermediate for chemicals, such as flame retardants and industrial dyes.

It is not manufactured in the EU but imported in volumes of 10,000-20,000 tonnes a year.

Echa opinion

The MSC opinion, adopted on 6 February, said France requested the substance to be reinserted into Corap for the same endocrine disruption concern due to "the changes in circumstances described in the justification document".

The committee noted that evaluation and regulation of endocrine disruptors are a priority for French authorities.

The MSC said that the conclusion that no action needs to be taken under substance evaluation by one member state "does not prevent another [...] from requesting the substance to be reinserted in the Corap, even if the available information on that substance has not changed".

Since no draft decision was issued by Finland, France "has had no opportunity in the [substance evaluation] process to formally react (using Proposals for Amendments) to Finland's assessment".

Echa told Chemical Watch it is yet to reply to the Resorcinol Task Force's letter.

Luke Buxton

Europe editor

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- Taskforce statement
- French Corap justification

Circularity and innovation key to European chemicals future

Investment in chemical recycling underway, says Cefic's Marco Mensink

27 March 2019 / Chemical production & transport, Europe

Driving the circular economy is key to the future of the European chemicals industry, the Chemical Watch Global Business Summit has heard.

In a keynote address to the two-day event in Brussels, Marco Mensink, Cefic director general, warned that the world is becoming far more fragmented and for the industry to thrive it has to stop complaining about regulatory burden and "develop its own solutions or we're sitting ducks".

"With our ageing society, we won't see any less pressure on chemical safety and health. On the contrary, as the work of Echa progresses the pressure will not decrease."

This, said Mr Mensink, is a problem because "we don't see this pressure elsewhere in the world". There is a significant difference between the US chemicals regulatory system and Europe's, as well as other countries, and some do not even have the UN's Globally Harmonised System (GHS) for classification and labelling .

Fragmentation is breaking the world down into different regions, for example Chinese, African and American worlds, Mr Mensink said.

"We need to see what we can do that others can't," he added.

'Circularity is key. We have a vast resource in Europe that we're not using today: waste'

"We won't beat the US on shale gas and lawyers, or the Chinese on the number of engineers. So we have to ask what will be the European thing that drives us forward?

"Circularity is key. We have a vast resource in Europe that we're not using today: waste. Make Europe the Bangladesh of the world and recycle every ship we have. Why not massively invest in chemical recycling? Which is what the chemical companies are doing as we speak."

Glass, metals and paper have taken the lead and the chemical industry is just catching up, Mr Mensink said. "Chemical recycling will take care of a number of legacy chemicals that we don't know what to do with."

Europe must be thought of as a "gigantic source of feedstock".

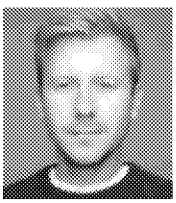
Integration

And, he said, the industry should look at integrating its operations with other sectors, for example steel production where waste gases could become a 'feedstock' for chemical companies.

"Today we have 30 companies working on chemical recycling across Europe."

"We want to be the canary that survives the coal mine," Mr Mensink concluded, calling on Europe to lead the way across the globe with "new kinds of chemistry, new kinds of waste, and engaging in a lot of debates".

At last year's Helsinki Chemicals Forum, Mr Mensink called for a "smart REACH foreign policy". Cefic will be launching its mid-century strategy on 25 June.



Leigh Stringer
Global Business Editor

Related Articles

- Cefic head urges 'smart REACH foreign policy'

New Jersey legislature passes asbestos in products ban

28 March 2019 / CMRs, US states

The New Jersey legislature has unanimously approved a bill to ban the sale or distribution of any product that contains asbestos.

The bill (A 4416) passed the Senate on a 35-0 vote last month. The assembly agreed the final version on 25 March by a 76-0 margin.

The legislation would authorise the state's Department of Environmental Protection the right to enter a business to determine compliance with the act. Violations are subject to a penalty of up to $2,500 per offence.

If signed into law by New Jersey governor Phil Murphy, the prohibition will take effect on the first day of the fourth month following its enactment.

Further Information:

- A 4416 (bill lookup)

US EPA round-up

28 March 2019 / Solvents, Substance notification & inventories, TSCA, United States

EPA formally publishes methylene chloride rule, workplace programme proposal

The EPA has published in the *Federal Register* its final rule prohibiting the manufacture, processing and distribution in commerce of methylene chloride for use in consumer paint removal products.
The rule takes effect on 28 May, with a retail prohibition taking effect 180 days later.

A separate *Federal Register* notice has begun a consultation on a proposal to develop a workplace programme that would impose training, certification and limited access requirements for methylene chloride use in commercial coat and painting removal.

Comments on the Advanced Notice of Proposed Rulemaking (ANPRM) will be accepted until 28 May.

TSCA 'not likely' findings

The US EPA has issued nine TSCA 5(a)(3)(c) findings for substances subject to pre-manufacture notices (PMNs). These "not likely to present an unreasonable risk" determinations will allow the substances to come to market without restriction.

They cover:

- P-19-0009: a polymer intended to be imported in solution for use as a corrosion protective additive;
- P-18-0284: an inorganic acid, reaction products with alkyl alcohol, intended for use as a polymer composite additive;
- P-18-0278: isophthalic acid, polymer with terephthalic acid and C4 and C6 dialkyl amines, imported for use as a resin for molded automotive parts and electrical equipment;
- P-19-0025: 11-docosene, manufactured for use as a hydrophobe formulation;
- P-19-0021 and P-19-0022: confidential polymers intended for use in pigment ink;
- P-19-0002: a polyaromatic symmetrical tetracarboxylic acid manufactured for use as a chemical intermediate;

- P-18-0272: a confidential substance, generically described as metal, alkylcarboxylate oxo complexes, intended for use as a polymer composite additive;
- P-18-0169: a polymer manufactured for use as a protective coating; and
- P-17-0119: a confidential polymer imported for use as a component of industrial coatings.

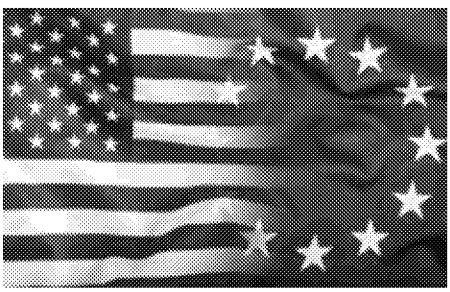
Related Articles

- US EPA bans methylene chloride in consumer paint removers
- US EPA seeks comments on workplace programme for methylene chloride
-
- **Further Information:**
-
- Methylene chloride final rule
- Methylene chloride workplace proposal
- TSCA 'not likely' findings

US asks EU to postpone titanium dioxide, cobalt metal classifications

Concerns over trade implications, transparency of WTO notification

27 March 2019 / Classification, CLP Regulation, Europe, Substances of concern, United States



The US has asked the EU to postpone its proposal to classify titanium dioxide and cobalt metal as carcinogens, warning that these moves may be "unnecessarily disruptive to billions of dollars of US-EU trade."

In a statement to the World Trade Organization (WTO) on 21 March, the US called for a clarification on why titanium dioxide, which is labelled as 'low toxicity' in Echa's scientific Opinion, was being classified as a category 2 carcinogen.

It says the US is concerned that products containing the substance, including paints, cosmetics and plastics, will have to be reformulated or labelled as containing a carcinogen.

And it asks if the EU is diverging from the GHS for titanium dioxide and if so why, given that there are "far less trade disruptive alternatives".

The EU draft proposal restricts the classification mainly to mixtures in powder form, based on the argument that titanium dioxide-induced carcinogenicity is only associated with inhalation.

However, a decision on the substance's CLP entry has been delayed several times amid accusations from NGOs that the Commission has diverged from Echa's Risk Assessment Committee (Rac) Opinion for the classification of all forms of the substance.

Industry body the Titanium Dioxide Manufacturers Association (TDMA) has made a strong case against classification, saying that the suspected hazard as described by Rac is not intrinsic to the substance and is unlikely to occur in real-life situations.

It said a Commission expert meeting last April had confirmed this view and concluded that the hazard outlined in Rac's Opinion does not exist in consumer products. TDMA is calling for a different regulatory mechanism for titanium dioxide, such as workplace legislation.

Commission sources have said it is pursuing the classification route and will look for a vote during one of the next REACH Committee meetings.

Cobalt metal

The US notification also raises concerns about the Commission's proposed classification of cobalt metal as a category 1B carcinogen.

Rac adopted an Opinion in 2017 for the harmonised classification and labelling (CLH) for all routes of exposure but, last year, the metals industry asked for more time to address concerns about specific concentration limits.

Echa responded to industry concerns in November, saying it would review the methodology used.

The US statement to the WTO says: "We do not understand why the Commission is rushing towards a restriction on the presence of cobalt in metal compounds." It asks the Commission to "consider delaying" the inclusion of metal compounds in the classification until the necessary testing is completed.

If the restriction goes ahead, it adds, it will affect US exports of medical products and food processing equipment to the EU, since the stainless steel in them contains 2-3% cobalt, which cannot be removed.

It is asking the EU to postpone its vote on both titanium dioxide and cobalt metal.

It has also asked Echa to clarify what products and articles, in addition to the chemicals, will be impacted by the proposed measures.

The US statement also questions the transparency of the EU's notifications to the WTO, saying it was disappointed that the Commission "rushed" to finalise the measure on titanium dioxide without meaningful consideration of WTO member comments.

The Commission's notification received over 400 via the WTO and the EU's Better Regulations consultation, it says, but the Commission met to vote on the draft regulation only four days after the WTO comment period closed.

It is asking the EU to undertake a review of the comments.

Clelia Oziel
Europe correspondent

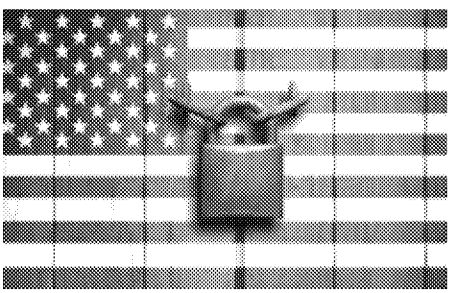
Related Articles

- EU titanium dioxide classification proposal hits waste obstacle
- Rac opinion makes candidate list unlikely for titanium dioxide
- Echa agrees to review cobalt classification method
- Echa's risk committee focuses on carcinogen occupational exposure
-
- **Further Information:**
-
- WTO statement

TSCA data release does little to end PV29 controversy

EPA faulted for redaction in studies protected as confidential

28 March 2019 / Confidentiality & right-to-know, TSCA, United States



The US EPA's decision to release additional information underlying its TSCA risk evaluation of pigment violet 29 has not ended the ongoing controversy around the confidentiality of health and safety data, Chemical Watch has learned.

The EPA last week announced it had published the information underpinning its November 2018 draft evaluation for PV29, including 20 studies submitted to Echa when the substance was registered under REACH.
The move came after public outcry and a December public records request, pressing for the release of 24 studies that had originally been withheld as confidential business information (CBI).

But in an interview with Chemical Watch, Richard Denison said there are "still significant redactions" in the information that EPA has made public.

For example, he said the study the PV29 risk evaluation relied on most heavily – a reproductive and developmental toxicity screening test – has 333 of its 430 pages fully redacted.

"All of the data in the study are blacked out," he said. "There is simply no way to know whether that study says what EPA and the company says it did without that data," he added.

Another problem, he said, is that the EPA has published a 10-page document of "summaries" covering ten of the studies, rather than the full versions. And he said this compilation appears to have been prepared by the data owner, BASF.

The concern here is twofold, said Dr Denison. First, the public is being forced to rely on a company's own interpretation of its studies. And second, it raises the question of whether the EPA itself has access to the full studies.

> *'The release of these study reports should not be mistaken for transparency by EPA,' the Natural Resources Defense Council's Jennifer Sass*

"This is what [the EPA] has apparently declassified and made public," he said. "Does EPA only have these summaries of these ten studies? If so, then that's troubling."

The Natural Resources Defense Council's Jennifer Sass agreed: "The release of these study reports should not be mistaken for transparency by EPA – in fact, it shows that EPA is actively suppressing information and violating the requirements of TSCA.

"The study reports are either too short or too redacted to be useful," she said.

The American Chemistry Council, however, defended the agency's approach.

"EPA appropriately redacted CBI, when properly substantiated by study owners, to protect commercially valuable information in its public release of the PV29 health and safety studies," said the trade group. "We expect this is how the agency will proceed in the future as it is the correct approach."

> *'Companies will be reluctant to give EPA REACH studies, fearing loss of data compensation rights,' Herb Estreicher, a partner with law firm Keller and Heckman*

Meanwhile, Herb Estreicher, a partner with law firm Keller and Heckman, told Chemical Watch he found the EPA's decision to release the studies "very troubling".

"Companies will be reluctant to give EPA REACH studies, fearing loss of data compensation rights," he told Chemical Watch. "This will detract greatly from the quality of future TSCA risk evaluations and/or lead to unnecessary duplication of animal testing."

The Physicians Committee for Responsible Medicine, which has been a vocal advocate for reducing animal testing, said in a statement it fully supports the sharing of test data to meet regulatory needs, as well as making it publicly available where possible.

"In this case, the EPA reviewed the remaining [CBI] claims … and determined that some information is entitled to protection, which was redacted from the publicly released studies," said the PCRM's Kristie Sullivan.

Beck: More controversy to come?

In an interview, following her public remarks at the Chemical Watch Global Business Summit in Brussels this week, the EPA's Nancy Beck weighed in on whether confidentiality disputes under TSCA are only beginning.

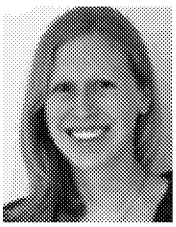
Ms Beck, principal deputy assistant administrator at the EPA's Office of Chemical Safety and Pollution Prevention, said the agency thought that PV29 was "uncontroversial". But it has proven a challenge, she said, because "some of our stakeholder groups don't understand how, with only screening level information, we can say something is safe."

"Part of it is on us [the EPA] to do some education about screening level approaches and how we do decision making, but in the US it's called the unknown unknowns," she added.

But with respect to the additional nine draft evaluations that the EPA is planning to release in the coming weeks, she said the same CBI issues might not be in play.

"Because PV29 is a data-poor chemical [that] nobody's really studied a lot, the information did have to come from the companies," she said. "For the rest of the first ten – asbestos, [trichloroethylene], methylene chloride – there are thousands of articles in the public literature," so this same CBI concern is not likely.

But she added: "I think when we finish the first 100 chemicals and then get to the later ones, you'll have this issue [again]."



Kelly Franklin
North America editor

Related Articles

- US EPA publishes REACH studies underlying TSCA PV29 evaluation
- First TSCA draft risk evaluation finds no unreasonable risk
- Democrats call for release of CBI data underlying TSCA evaluation
- NGOs demand release of REACH studies submitted as confidential under TSCA
- EPA names first ten chemicals for new TSCA evaluations

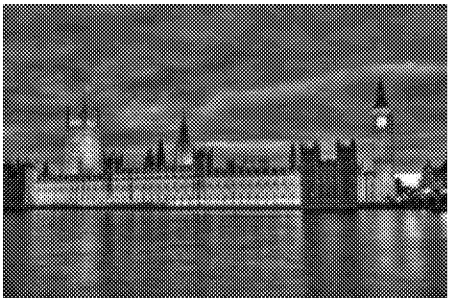
- **Further Information:**

- PV29 studies
- Reprotox study
- Study summaries

UK Parliament motion opposing draft REACH statutory instrument withdrawn

'Motion of regret' over lack of participation in Echa passes

28 March 2019 / Brexit, REACH, UK



Liberal Democrat peer Christopher Fox has withdrawn a House of Lords motion intended to kill the draft UK REACH statutory instrument (SI) at the last minute prior to a vote.

The House of Lords is the second, unelected, chamber of the UK Parliament and shares the task of making laws and overseeing the government's work.

Speaking during a House debate on 26 March, he said that the government "can live" with the regulation in the future, but the SI is "deeply flawed and that the country would suffer" if it was implemented.

Instead Lord Fox said he supported another motion by Labour peer John Whitty, which reflects concernsraised by industry.

Lord Whitty's motion passed by 214 votes to 202. It is an amendment to express 'regret' that the draft regulations fail to fulfil the government's intention to maintain the UK's participation in Echa.

It also calls on the government to make continued UK participation in Echa and REACH "an objective in negotiations with the European Union".

The SI, which sets out the UK regulatory regime in the event that it leaves the EU without a deal, passed through the House of Commons in February. Had Lord Fox's motion passed, the instrument would have had to be pulled back.

A so-called 'motion of regret' cannot stop or amend the SI, but gives members an opportunity to put on record their dissent.

The SI transfers the role of Echa to the Health and Safety Executive (HSE), and requires it to seek scientific advice to inform its assessments, and transfers decision-making powers currently held by the European Commission to the secretary of state for environment.

Debate

During the debate, Robin Teverson, a Liberal Democrat peer and the chair of the EU Energy and Environment subcommittee, highlighted concerns about "significant additional resources" that the HSE will need, the extra costs businesses will face, and the fact it will be impossible to avoid duplicating some animal testing.

These issues will particularly affect SMEs and a much broader supply chain beyond chemical manufacturers themselves, he said. Although the Department for the Environment, Food and Rural Affairs' (Defra) approach has improved, he added "we are far from having a satisfactory regime at this time".

The Lords had noted their concerns in a report *Brexit: chemical regulation,* which said in November that preparations were not progressing quickly enough, with potentially severe consequences for industry.

Industry reaction

The Chemical Business Association (CBA) said it was disappointed that Lord Fox chose to withdraw his motion. It had "broad support" from industry and would have required Defra to consult it before bringing forward alternative proposals for UK REACH.

Industry can take some comfort from Lord Whitty's motion of regret, chief executive Peter Newport said. Continued participation in Echa would "remove the need for this ill considered" SI, he added.

John Hibbs, chair of the British Association for Chemical Specialities (Bacs), said: "We would like to thank Lord Fox for his attempt to force a reconsideration of this deeply flawed regulation, but yet again Defra have shown that while they invite comment, they are not listening."

And Nishma Patel, director at the UK's Chemical Industries Association, said that the draft REACH SI is the "most unclear piece of law the industry has ever had to work with". She urged the government to "take note and act quickly" on the points raised in the House of Lords.

Clelia Oziel
Europe correspondent

Related Articles

- Lord tables motion opposing UK draft REACH statutory instrument
- UK REACH database still up in air, government admits
- 'Significant' Brexit concerns remain, UK Lords tell government
- UK government pressed to clarify post-Brexit REACH approach

- **Further Information:**

- Lord Fox motion
- Lord Whitty motion
- Draft REACH SI

Efsa publishes final version of mixtures guidance

28 March 2019 / Europe, Food & drink, Mixtures

The European Food Safety Authority has finalised its guidance on risk assessment of chemical mixtures.

The 77-page document, published on 25 March, provides a "harmonised framework" for Efsa expert groups tasked with the evaluation of combination effects. The guidance is also intended to support and inform risk managers.

Public consultation on the draft version in 2018 generated 273 comments from 25 parties.

The comments, plus Efsa's responses, are available in a technical report, also published on 25 March.

In most cases, chemicals legislation is predicated on a substance-by-substance approach to risk assessment and does not require regulatory authorities to consider combination effects. In the real world, however, chemical exposures usually involve mixtures rather than individual substances, making combination effects potentially relevant for the determination of risk.

Because of this, some academics have argued for changes to legislation, despite broad acceptance that there remains an acute need for more data on mixtures, particularly relating to exposure.

Related Articles

- Efsa consults on mixture assessment
- Kortenkamp boosts calls for legal mandates for mixture risk assessment

- **Further Information:**

- Guidance
- Technical report on comments

Proactive Alliance splits into groups to progress chemical reporting goal

One aim is to establish criteria for a common 'Substance Reporting List'

28 March 2019 / Confidentiality & right-to-know, Data, Europe

Cross-sector industry group, Proactive Alliance, has created four sub-groups that will help it establish a global standard for companies to report on substances in articles along the supply chain.

The group is made up of representatives from a number of sectors, including automotive, chemicals, electrical and electronic, furniture and textiles.

It formed at Chemical Watch's Global Business Summit in Amsterdam in 2018 to address the growing number of requirements from regulators and companies to communicate substances in articles (SiA).

Speaking this week at this year's Global Business Summit in Brussels, Stephane Content, Cefic's product stewardship manager and member of the PA, announced the aims of the four working groups.

These will:

- deal with the harmonisation of the criteria for establishing a Substance Reporting List (SRL);
- harmonise reporting formats on how to declare substance information;
- draw up the terms of reference or determine the rules of procedure; and
- reach out and invite organisations around the world to join PA's work.

Mr Content said that, without an SRL, it is "not possible to collect efficient substance data, and confidential business information (CBI) is difficult to protect".

"The more harmonised the sector/company SRLs are, the more efficient data collection can be and less individual work is required," he said.

Working Group one has proposed six criteria for the development and maintenance of SRLs. They define the scope of:

- a substance;
- the legislation;
- the jurisdiction;
- the application;
- the threshold; and
- the format and content of an SRL.

Outreach

Working group four has not yet started its outreach work. "So far we have only discussed this with trade associations within Europe," said Mr Content.

The group will connect with other initiatives around the world, including standardisation bodies. However, inviting colleagues outside of the original group now would "create great complexity, which is why it is already split into four sub-groups," he said.

"Having a discussion with 25 people on such a difficult topic is complex but if you include Japanese, Chinese, US and other colleagues we could end up with a hundred people in the group and this is not practical.

"So when we have something more presentable, hopefully next year, then we can open up to our national and regional colleagues," he said.

The PA has two face-to-face plenary meetings a year, as well as coordination meetings and lastly the sub-group meetings.

"We realised that when we started talking about these difficult issues, we needed experts to focus on specific areas. And this is why we have divided the large group into sub-groups," he said. These will feed back to a coordination group, which will in turn communicate the outcomes to the plenary.

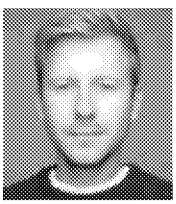
Outcomes from the four groups will be available by the second quarter of the year. The PA says these will feed into a draft policy document.

It aims to present the draft policy recommendations at Chemical Watch's Global Business Summit next year. It will then put these recommendations to the fourth International Conference on Chemicals Management (ICCM) in Bonn in October 2020, where the future of the global voluntary programme, the Strategic Approach to Chemicals Management (Saicm), will be decided.

Speaking alongside Mr Content, Martin Führ, a professor at Darmstadt University of Applied Sciences, who is coordinating the initiative with his research group Sofia, told the summit: "There is a momentum towards this direction of transparency, traceability and to increase trust among professionals and citizens, as well as to improve communication along the supply chain."

Referring to earlier discussions about the importance of achieving circular business models, Dr Führ said that without these elements the idea of circularity is not possible.

In February, the PA published a mission statement, setting out its plan to establish a global standard to report substances in articles.



Leigh Stringer
Global Business Editor

Related Articles

- Industry representatives start talks on cross-sector material declarations
- Feature: Has the Saicm programme made any difference?
- Cross-sector alliance sets out chemical reporting objectives

EU consults on REACH transitional rules for certain substances

28 March 2019 / Data, Europe, REACH, Substance registration

The European Commission is requesting feedback on a draft implementing Regulation that proposes transitional deadlines for certain phase-in substances following the final REACH registration phase.

Article 23 of REACH established a transitional regime for phase-in substances, laying down a number of different deadlines for registration of these chemicals.

To ensure equality between market operators manufacturing or placing on the market phase-in and non-phase-in substances, the draft Regulation says it is necessary to "specify the applicability, after the expiry of the transitional regime, of provisions that laid down favourable conditions for the registration of phase-in substances".

It proposes an "appropriate, reasonable and clear cut-off date" of 31 December.

The draft text addresses the applicability of the date to:

- low volume substances, including new toxicological and ecotoxicological information for priority substances;
- data-sharing obligations; and
- data-sharing dispute processes.

The consultation runs from 26 March to 23 April.

Related Articles

- More than 21,000 substances registered under REACH

- **Further Information:**

- Consultation

EDC-MixRisk finds relevant chemical mixtures for risk assessment

'Significant step' towards simplifying process

28 March 2019 / Europe, Mixtures

EU Horizon 2020-funded project EDC-MixRisk has identified a small number of chemical mixtures that are relevant to a large proportion of the population, which could provide a simpler way to assess the risks of mixtures.

"This is a significant step forward as it is not feasible to test all possible combinations of different mixtures," an EDC-MixRisk policy brief states.

The research project ended in January 2019. Coordinated by Ake Bergman from the Karolinska Institute in Stockholm, Sweden, the project studied the effects of prenatal exposure to mixtures of suspected endocrine disrupting chemicals (EDCs) on child health and development.

EDC-MixRisk identified and tested "real-life" EDC mixtures. By using epidemiology data from the Swedish Environmental Longitudinal Mother and Child, Asthma and Allergy (Selma) study, researchers created reference mixtures to mimic real-life exposures. They then tested them in cell and animal models for potential adverse effects in terms of growth and metabolism, neurodevelopment and sexual development.

The results suggest that single chemical assessments could be underestimating the risks for mixtures from one to tenfold.

Importantly, the project found that 80% of the women were exposed to real mixtures that were similar to the reference mixture.

The policy brief suggests that the project's methods could "significantly contribute to more relevant risk assessment and management by providing more reliable empirical information and better reflecting real life scenarios".

EDC-MixRisk launched its policy brief as part of a workshop, 'The chemical cocktail challenge,' in Brussels, on 26 March 2019. The workshop was organised jointly with the EuroMix project.

Related Articles

- Applying science to mixtures
-
- **Further Information:**
-
- Press release
- Policy brief
- EDC-MixRisk

OTHER ARTICLES

Green Chemicals Market Growth Forecast Analysis by Manufacturers, Regions, Type and ...
regionnewsonline.com (blog)
The Global **Green Chemicals** Market Forecast 2024 Report Description: **Green chemicals** or bio-based chemicals are renewable chemicals produced ...

New study links **chemical** sunscreens to birth defects
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There is growing concern over the **toxicity** of **chemicals** used in the formulas, primarily oxybenzone and octinoxate, and the harm they cause both to ...